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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,101	04/08/2004	Agostino Tucciarone	AT-11	1706

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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,101	TUCCARONE ET AL.	
	Examiner	Art Unit	
	Mary Hoffman	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-19 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19 and 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Applicant is again reminded that a claim for foreign priority under 35 U.S.C. 119(a)-(d) cannot be based on British application GB 0208667.6, since the United States application was filed more than twelve months thereafter. The effective filing date is being considered 4/15/2003, which is the date of filing of PCT/GB03/01606.

Certified copies of the prior applications as required by 35 U.S.C. 119(b) have been received.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 32, applicant recites "A method according to claim 15, wherein said transverse suspension device is configured as shown in Figure 3." The scope of this claim is unclear.

Claim Objections

Claim 30 is objected to because of the following informalities: In claim 30, "angel" should be changed to --angle--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

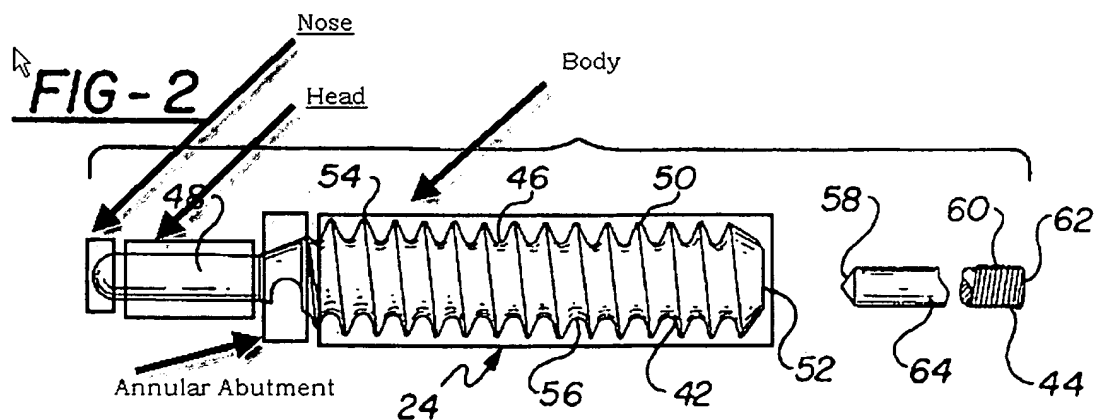
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-23, 25-28, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Howell et al. (U.S. Patent No. 5,674,224).

Howell et al. disclose a method of ACL graft ligament fixation comprising the steps of providing a transverse suspension device comprising a proximal body section defining a longitudinal axis, a head section extending along the longitudinal axis and protruding distally from the body section, the head section having a smaller diameter than that of the body section, and an annular abutment surface disposed between the head section and the body section wherein the abutment surface is substantially at an angle to the longitudinal axis (FIGS. 2-3); forming a femoral tunnel and forming a transverse tunnel intersecting the femoral tunnel (FIG. 10); locating a graft loop in the femoral tunnel in such a manner that an open face of the loop faces an intersection

Art Unit: 3733

where the femoral tunnel intersects the transverse tunnel FIGS. 11-12); passing at least a part of the head section of the transverse suspension device through the graft loop via the transverse tunnel until the head section contacts a recess formed in an opposite wall of the femoral tunnel wherein the abutment surface urges the graft against the opposite wall (FIG. 14). A guidewire is advanced under observation with a viewing device, specifically an arthroscope (col. 6, lines 37-53). The recess is formed with a dilator tool (ref. #124). The transverse suspension device is cannulated. The transverse tunnel is drilled to intersect and not cross the femoral tunnel. The body section comprises external threads. The device includes a nose section distal to and distinct from said head section and having a reduced diameter as compared to said head section, said nose section extending along said longitudinal axis, and an annular abutment surface distinct from said head section and disposed between said head section (see marked up figure below). The angle is about 90 degrees and the head section has a substantially constant diameter.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al. (U.S. Patent No. 6,499,486) in view of Clark et al. (U.S. Patent 6,306,138).

Chervitz et al. disclose a method of ACL graft ligament fixation comprising the steps of forming a passing pin tunnel in a femur (FIG. 10), the passing pin tunnel having a longitudinal axis and exiting a superior wall of the femur; forming a femoral tunnel along the longitudinal axis, the femoral tunnel having a larger diameter than the passing pin tunnel and terminating in the femur; forming a transverse tunnel intersecting the femoral tunnel; locating a graft loop (ref. #25) in the femoral tunnel in such a manner that an open face of the loop faces an intersection where the femoral tunnel intersects the transverse tunnel, and wherein the locating comprises pulling on sutures (ref. #100) holding the graft loop to locate the graft loop, and the pulling on sutures comprises pulling on the sutures through the passing pin tunnel; passing at least a part of a head section of a transverse suspension device (see FIG. 4) through the graft loop via the transverse tunnel until the head contacts an opposite wall of the femoral tunnel. After location of the graft loop in the femoral tunnel, a guide wire is advanced thereunder from

Art Unit: 3733

the transverse tunnel (FIG. 11). The suspension device is passed along the guide wire after the guide wire is advanced under the graft loop. The head of the device is advanced as far as a distal head of a recess (channel opposite to transverse channel) formed in the opposite wall of the femoral tunnel. The graft is urged against the opposite wall as the head is advanced into the recess.

Chervitz et al. disclose the claimed method except for the transverse tunnel terminating within the femur; rather Chervitz shows a tunnel that accommodates a flexible guide wire.

Clark et al. disclose a traditional guide wire, ref. #18, which does not require the transverse tunnel to exit the femur, thus, Clark et al. disclose the transverse tunnel terminating within the femur (FIG. 13) for delivering the guide wire and cross pin under the graft loop.

It would have further been an obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Chervitz et al. with the transverse tunnel terminating within the femur in view of Clark et al. for delivering the guide wire and cross pin under the graft loop.

Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al. (U.S. Patent No. 5,674,224).

Howell et al. discloses the claimed invention except for the nose section being frustoconical shaped. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the head section of Howell et al. being frustoconical shaped, since applicant has not disclosed that such

solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a head section or ligament holding nose of a transverse suspension device. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al. (U.S. Patent No. 5,674,224) in view of Clark et al. (U.S. Patent 6,306,138).

Howell et al. discloses the claimed invention except for the nose section being frustoconical shaped and the step of passing being performed subsequent to locating.

Clark et al. disclose the step of passing being performed subsequent to locating (see FIG. 13) through the use of a tendon passer so that the cross pin will capture the tendon (graft).

It would have further been an obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Howell et al. including the step of locating the graft being prior to passing of the transverse member through the use of a tendon passer in view of Clark et al. so that the transverse member will capture the tendon. It would have further been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the head section of Howell et al. being frustoconical shaped, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a head section or ligament holding nose of a transverse suspension device. In re Dailey and Eilers, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments with respect to claims 15-19 and 29 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's other arguments filed 01/30/2007 have been fully considered but they are not persuasive.

Applicant argues that the device of Howell et al. does not show a nose section, a head section, an abutment surface, and a proximal body section. As shown in the above marked up figure, the Howell et al. reference does disclose these features. It is noted that the recitation "distinct" is not sufficient to distinguish the current invention from the prior art, as one of the definitions of distinct is "distinguished as not being the same; not identical; separate" [Dictionary.com] and the Howell reference clearly shows this.

The rejection is deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 3733

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER